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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,217	02/10/2000	Howard Murad	2267-017	3548

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/28/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/501,217

Applicant(s)

MURAD, HOWARD

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9,11-23 and 25-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,11-23,25-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of request for reconsideration date 6-6-03 is acknowledged.

Double Patenting

Claims 1, 2, 4-9, 11-23 and 25-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Application no. 09/501,218. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims recite a method of managing dermatological conditions comprising administering a composition that reads on the instant composition. Instant claims also recite the same utility as of the copending claims. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the composition used in the copending method for the claimed utility of the instant invention i.e., for managing a dermatological condition.

Applicants stated in their response that this rejection, which has been previously made, would be addressed when either the present or the co-pending application is allowed. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-9, 11-23, 25-27 and 30-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Crotty (US 5,985,300) in view of Lansky (US 5,981,440) and Okaya (US 5,169,630).

Crotty teaches skin care compositions containing fruit extracts, zinc salts and other components such as ceramides, vitamins, mono- or polyhydroxy acids etc. See abstract, col. 4,

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lines 15-22 and col. 5, lines 12-40. In particular, Crotty teaches N-acetyl cysteine, which meets the requirement of instant cysteine component (col. 4, lines 10-14). Crotty teaches fruit extracts such as grape fruit, strawberry, vanilla fruit, blackberry fruit etc., as anti-oxidants and free-radical inhibitors (col. 3). Further, Crotty teaches herbal extracts for sebum/oil control include wheat (col. 4, lines 15-20), which reads on hydrophilic moisturizing agent and ceramides (abstract) as well as tocopherol linoleate (col. 4, lines 2-3). Crotty also teaches plant extracts such as rosemary, soy, Echinacea, ginkgo etc., phytoestrogens, herbal extracts, alpha- and beta-hydroxycarboxylic acids, anti-inflammatory, vitamins, flavonoids etc., all of which read on the claimed moisturizers, sunscreens, transition metals, anti-inflammatory agents, immunity boosting agents, ceramides, zinc salts etc. See col. 2, lines 40 through col. 5, lines 43, for individual vitamins, hydroxycarboxylic acids, plant or herbal extracts and other components. Crotty suggests adding phytoestrogens in their skin care compositions because of their antioxidant or free radical inhibiting activity. See table in col. 3. However, Crotty fails to teach pomegranate extract and manganese ascorbate of the instant claims.

Lansky teaches pomegranate extracts in topical composition for supplementing phytoestrogens. Lansky teaches extracting pomegranate seeds and admixing with other herbal extracts such as licorice (col. 4), adding carriers such as beeswax, cocoa butter, citric acid (col. 6, lines 37-38 and 61) and using the composition as a skin cream (abstract, col. 2, lines 3-36) for treating oily skin (col. 2, lines 20-23). The phytoestrogens of schizandra berries (col. 4, lines 1-3) read on other antioxidant of instant claim 20. Lansky teaches topical as well as oral administration of phytoestrogens. Lansky fails to teach pomegranate extract in an amount sufficient to neutralize free radicals. However, claim 2 recites teaches the amount as 0.01 to 80

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weight percent and Lansky teaches 1% to 10% (col. 7, lines 18-22). Thus, the amount of pomegranate extract (of Lansky) is in sufficient amounts to neutralize free radicals. Cocoa butter and beeswax of Lansky read on the hydrophobic moisturizing agents and hydrophilic lanolin (col. (col. 7, line 3) read on hydrophilic moisturizing agents.

Lansky and Crotty fail to teach manganese ascorbate of instant claims.

Okaya teaches an external skin preparation comprising an aqueous preparation made of manganese containing superoxide dismutase (SOD) and a physiologically acceptable water soluble manganese salt, for preventing pigmentation, controlling aging and providing antioxidant activity (col. 1). Okaya further teaches the composition in the form of a lotion or ointment (examples). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use manganese salt (of Okaya) in the composition of Crotty containing pomegranate extract of Lansky because Okaya teaches that manganese salts and manganese-SOD provide antioxidant activity and protect skin from skin roughening. Among the manganese salts, Okaya et al teach manganese hydrochloride and manganese acetate, but not the claimed manganese ascorbate. However, Okaya teaches manganese salts as a stabilizer of SOD.

Examiner notes that instant specification also uses manganese for the same purpose.

Accordingly, absent any criticality of the specific salt, it would have been obvious within the scope of a skilled artisan to use any salt of manganese and still expect the same SOD protecting activity with the manganese salt and thus help skin moisturizing. Further, Crotty teaches adhesive strips but does not teach the composition in the form of topical lotion or ointment.

However, Lansky teaches using the same phytoestrogen containing composition for topical application and all the references are directed to skin care compositions. Accordingly, using the

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composition of Crotty containing the antioxidant pomegranate phytoestrogen of Lansky and manganese salt of Okaya, for topical applications i.e., in the form of a lotion or a cream and still achieve the antioxidant and moisturizing effect, would have been within the scope of a skilled artisan. With respect to claim 33, the term orally administered in the preamble does not carry patentable distinction because the claim is directed to a dermatological composition. Further, the cited references also teach dermatological compositions.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crotty (US 5,985,300) in view of Lansky (US 5,981,440) and US 5,759,555 to Moy.

Crotty and Lansky, discussed above, fail to teach copper sebacate of instant claim.

Moy teaches a composition for treating scaly, exfoliated skin conditions, and for treating skin fibrae distensae (weak collagen fibers) of photodamaged skin comprising unsaponifiable lipids from avocado seeds and metal chelates such as zinc and/or copper chelates (col. 2 & col. 7). Moy teaches zinc and copper amino acid chelates potentiate the effect of unsaponifiable fractionate of avocado seeds in treating photodamaged skin. Further, Moy also teach that the metal chelates are known for their wound healing activity. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add copper and/or zinc chelates of Moy in the skin care composition of Crotty containing pomegranate extract of Lansky because Crotty teaches a skin care composition for treating skin keratotic plugs and Moy also teaches for skin keratoses and the expected result would be to quickly heal the affected skin by the addition of copper and/or zinc chelates. Furthermore, while Moy fails t teach the claimed copper sebacate, absent showing criticality of the claimed copper salt, it is the

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position of the examiner that it would have been within the scope of a skilled artisan to use an appropriate copper chelate in the composition of Crotty and still achieve the same art recognized effect.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crotty (US 5,985,300) in view of Lansky (US 5,981,440) and US 5,804,167 to Schonrock et al ('167).

Crotty and Lansky, discussed above, do not teach the claimed selenium complexed with amino acid.

'167 teach a cosmetic or dermatological composition for functioning as a natural skin barrier and protect against environmental influences. '167 teach incorporating antioxidants as actives or additives in the composition (col. 3). Among the various antioxidants that are suitable, '167 teaches amino acids, their derivatives, alpha-hydroxyacids, ascorbic acid, vitamin E, vitamin A and their derivatives, metals such as zinc, selenium, in particular selenium methionine (reads on the instant selenium amino acid complex) (col. 4). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add antioxidant selenium methionine of '167 in the skin care composition of Crotty containing pomegranate extract of Lansky because Crotty is directed to a skin care composition comprising a number of antioxidants, Lansky teaches pomegranate extract as an antioxidant and '167 also teaches antioxidant in skin compositions for providing a natural barrier function for skin. Accordingly, one of an ordinary skill in the art would expect an additive effect in combining various known antioxidants i.e., pomegranate extract of Lansky and selenium amino acid complex of '167, in the composition of Crotty.

Response to ArgumentsDouble patenting rejection:

Applicants stated that the issue of double patenting rejection will be addressed either the instant or the co-pending application is allowed. Accordingly, the rejection has been maintained.

Claims 1, 2, 4-9, 11-23, 25-27 and 30-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Crotty (US 5,985,300) in view of Lansky (US 5,981,440) and Okaya (US 5,169,630).

Applicants argue that Crotty and Lansky fail to teach a composition containing manganese ascorbate and that Okaya fails to remedy the deficiencies of Lansky or Crotty because Okaya merely teaches that compositions containing Mn-SOD or modified Mn-SOD are more stable if the composition contains manganese salts. Applicants argue that manganese ascorbate of the instant claim 1 is not taught by Okaya or Crotty or Lansky. Applicants also argue that Mn-ascorbate perform dual functionality, both as Mn source and ascorbate salt- an antioxidant. However, Crotty already teaches incorporating vitamin C or salts or esters of ascorbic acid and as applicants themselves agree Okaya teaches manganese salts for the same purpose as that argued by applicants i.e., a co-factor for SOD in mitochondria. Further, Crotty teaches ascorbic acid as an antioxidant and Okaya also recognizes manganese salt for the same purpose. Therefore, combining two active agents for the same purpose would have been obvious for a skilled artisan. With respect to the argument that prior art does not teach hydrophobic and hydrophilic moisturizing agents in combination with pomegranate extracts and mono or polyhydroxy acid for treating dermatological disorders, instant claims merely state a composition

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and does not teach a method of treating a dermatological disorder. Further, all the references cited are directed to skin care compositions and Crotty teaches a variety of skin care agents such as ceramides, wheat protein, flax etc., which meet the claimed hydrophobic and hydrophilic moisturizing agents. With respect to applicants arguments regarding adhesive strips of Crotty, external compositions of Okaya and Lansky, and that none of them teach oral compositions, instant claims only recite oral in the preamble which does not carry patentable weight. Further, instant claims are not restricted to a specific form. Applicants' argument that examiner used hindsight reconstruction is considered but not persuasive because all the references cited are directed to skin care compositions and accordingly, the combination of the references for the skin care components flow logically.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crotty (US 5,985,300) in view of Lansky (US 5,981,440) and US 5,759,555 to Moy.

Applicants argue Moy does not teach copper sebacetate and instead only teach copper amino acid chelate. Accordingly, applicants argue that the combination of Moy with the teachings of Crotty and Lansky does not render instant claims obvious. However, applicants' arguments are not persuasive because instant specification state any copper component such as copper sebacetate. Applicants have not shown any criticality of the sebacetate salt of copper in the instant composition. On the other hand, Moy teaches copper chelates (which reads on a copper component) for treating stretch marks, keratoses and other skin lesions, which fall under instant dermatological conditions. Therefore, instant rejection has been maintained.

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Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crotty (US 5,985,300) in view of Lansky (US 5,981,440) and US 5,804,167 to Schonrock et al ('167).

Applicants argue that a mere disclosure of selenium complexed with amino acid, by Schonrock, does not render claim 29 obvious because the instant combination of pomegranate extract, selenium amino acid complex, hydrophilic and hydrophobic moisturizing agents and mono or polyhydroxy acids. However, Schonrock teaches selenium methionine as an antioxidant along with antioxidants such as vitamin C, vitamin E etc., which are also taught by Crotty. Therefore, combining active agents that are useful for the same effect i.e., antioxidant activity, with an expectation to at least provide an additive effect would have been obvious for a skilled artisan.

Examiner notes that instant claims are directed to a composition. However, applicants argue that the unexpected effects of a combination of pomegranate extract, hydrophilic and hydrophobic moisturizing agents and mono or polyhydroxy acids with manganese ascorbate or copper sebacetate or selenium amino acid complex is not taught by prior art. However, it is not clear to the examiner as to what effect applicants are referring to. Instant claims state 'for managing dermatological conditions' which is broad and applicants have not pointed to any specific unexpected dermatological results.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615
August 25, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

